IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. STEVEN J. ARNOLD, Defendant.	)	INFORMATION CASE NO. 1:23 CR 053 Title 18, United States Code, Section 1347 JUDGE ADAMS

FILED
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CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF OHIO
CLEVELAND

GENERAL ALLEGATIONS

At all times relevant to this Information unless otherwise specified:

Defendant and His Medical Practice

1. Defendant STEVEN J. ARNOLD was a medical doctor licensed by the State of Ohio Medical Board.

2. Defendant worked for Company 1 serving as the primary care physician and family medicine physician at a family medicine practice in Middlefield, Ohio, and managing the practice.

3. Persons who were patients of Defendant at his medical practice included Patient 1, Patient 2, Patient 3, Patient 4, and Patient 5 (known to the First Assistant United States Attorney, but not named herein).

Background Regarding Controlled Substance Prescribing

4. The Controlled Substances Act ("CSA") governed the manufacture, distribution, and dispensing of controlled substances in the United States. With limited exceptions, the CSA made it "unlawful for any person knowingly or intentionally" to "distribute or dispense . . . a controlled substance" or conspire to do so.

5. The term "controlled substance" meant a drug or other substance included in Schedules I, II, III, IV, and V of the CSA. The term "dispense" meant to deliver a controlled substance by, or pursuant to the lawful order of, a practitioner. It also included the prescribing and administering of a controlled substance. The term "distribute" meant to deliver (other than by administrating or dispensing) a controlled substance. The term "practitioner" meant a physician, medical doctor, dentist, or other person licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he or she practiced, to distribute or dispense a controlled substance in the course of professional practice.

6. Individual practitioners who wanted to distribute or dispense controlled substances in the course of professional practice were required to register with the Attorney General of the United States before they were legally authorized to do so. Such individual practitioners were assigned a registration number by the United States Drug Enforcement Administration ("DEA").

7. Practitioners registered with the Attorney General were authorized under the CSA to write prescriptions for, or to otherwise dispense, Schedule II, III, IV, and V controlled substances, so long as they complied with the requirements of their registrations. 21 U.S.C. § 822(b).

8. As a medical doctor licensed in Ohio, Defendant was a "practitioner" within the meaning of the CSA. Defendant was also registered to prescribe controlled substances under a unique DEA registration number.

9. For medical doctors, compliance with the terms of their registrations meant that they could issue a prescription for a controlled substance to a patient only if the prescription was

"issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice." 21 C.F.R. § 1306.04(a).

10. The scheduling of controlled substances was based on each substance's potential for abuse, among other considerations. Drugs that had a high potential for abuse and could lead to severe psychological or physical dependence were classified as Schedule II controlled substances. Drugs that had a lower potential for abuse and could lead to limited physical or psychological dependence were classified as Schedule IV controlled substances. 21 U.S.C. § 812.

11. Oxycodone, hydrocodone, and methadone belonged to the opiate analgesic class of drugs used to treat moderate to severe pain. These drugs were commonly called opioids and were listed as Schedule II controlled substances with a high risk of addiction and abuse. Oxycodone was sold under the brand names OxyContin, Oxy-IR, and Roxicodone. Oxycodone was combined with acetaminophen and sold under the brand name Percocet. Hydrocodone was combined with acetaminophen and sold under the brand name Norco.

12. Diazepam and alprazolam belonged to a class of drugs called benzodiazepines and were listed as Schedule IV controlled substances. These drugs were used to treat anxiety, seizures, and insomnia. They were sold under brand names Valium and Xanax.

13. Methadone is a synthetic opioid that can be prescribed for pain reduction or for use in medication-assisted treatment (MAT) for opioid use disorder. For MAT, methadone is used under direct supervision of a healthcare provider.

14. Prescription drugs, such as those containing the opioids hydrocodone, oxycodone, or methadone or the benzodiazepines alprazolam or diazepam, could be sold on the illegal secondary market, such as at the street level, for significant sums of money.

15. Controlled substances prescribed in certain dangerous combinations often produced dire effects on patients. In 2016, the United States Centers for Disease Control and Prevention ("CDC") recommended that physicians avoid prescribing opioids and benzodiazepines in combination—such as oxycodone, hydrocodone, or morphine, with diazepam or alprazolam—whenever possible. Together, the drugs caused severe respiratory depression, including leading to death.

16. The strength or dose of opioid controlled substances was often measured through Morphine Milligram Equivalents ("MME," sometimes also referred to as morphine equivalents or "MEQ"). The MME measurement first converted various opioid class drugs to morphine milligram equivalents based on a conversion factor of the strength of the opioid (using Morphine as a base of 1). The MME per day, referred to as the Morphine Equivalent Dose ("MED"), measured a patient's daily dosage of opioids based on the MME conversion for each controlled substance and the quantity of the controlled substance or substances prescribed per day. The MED measurement allowed for a relative comparison of patients' cumulative intake of opioid class drugs over 24 hours, based on the type and quantity prescribed. The CDC have medically determined the relative strength of opioids and made the list publicly available. CDC guidance issued in 2016 set a prescribing threshold of 90 MED for a patient at a given time, and instructed that clinicians should establish incremental benefits to pain and function to justify an increase to 90 MED or greater, due, in part, to increasing risk of patient overdose.

17. Over 30% of opioid overdoses involved benzodiazepine use. On August 31, 2016, the United States Food and Drug Administration ("FDA") issued a "black box" warning for prescribing opioids in combination with benzodiazepines. The warning stated in part:

> FDA is warning patients and their caregivers about the serious risks of taking opioids along with benzodiazepines or other central

> nervous system (CNS) depressant medicines, including alcohol. Serious risks include unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, coma, and death. These risks result because both opioids and benzodiazepines impact the CNS, which controls most of the functions of the brain and body.

18. To ensure that they were issuing prescriptions for a legitimate medical purpose in the usual course of their professional practice, physicians often monitored patients' use of prescribed and non-prescribed substances by requiring patients to whom they prescribed opioids to submit urine samples for laboratory analysis. Such a urine drug screen ("UDS") tested for the presence of non-prescribed controlled substances, which could negatively interact with prescribed controlled substances to cause injury to, or death of, patients. A UDS also tested for the presence or absence of the controlled substances that the physicians were prescribing to their patients. When a UDS failed to detect the presence of a prescribed drug, it suggested that the patient was not taking the drug as directed in the prescription. Results indicating the absence of a prescribed substance suggested that the patient was abusing the drug by taking it too frequently and in greater amounts than prescribed, or that the patient was diverting the drug by selling it for profit on the illegal secondary market.

Background Regarding Healthcare Benefit Programs

19. Medicaid was a federal health care benefit program designated to provide medical services to certain individuals and families with low income as outlined in the Social Security Act (Title 42, United States Code, Section 1396 et seq.). Medicaid was a health care benefit program within the meaning of Title 18, United States Code, Sections 24(b) and 1347.

20. While the Federal Government funded large portions of Medicaid, the program itself was largely administered by the states. The Ohio Department of Medicaid ("ODM") administered Medicaid in Ohio, and it received historically approximately 60% of its funds from federal sources. Ohio providers claimed Medicaid reimbursement from ODM pursuant to

written provider agreements. ODM received, processed, and paid those claims according to Medicaid rules, regulations, and procedures.

21. A Medicaid Managed Care Organization ("Medicaid MCO") was a private managed care organization that contracted with ODM pursuant to Ohio Revised Code Section 5164.85 to provide Medicaid services. Medicaid MCOs were health care benefit programs within the meaning of Title 18, United States Code, Sections 24(b) and 1347.

22. MCO 1 and MCO 2 were Medicaid MCOs operating in Ohio.

23. Medicaid and Medicaid MCOs prohibited payment for items and services that were not "reasonable and necessary" to diagnose and treat an illness or injury. Pursuant to the rules and regulations of the Ohio Medicaid Program, including Medicaid MCOs, Medicaid only paid for services that were actually performed by qualified individuals, were medically necessary, and were provided in accordance with federal and state laws, rules and regulations. Medicaid and Medicaid MCOs required providers to certify that services were medically necessary. Only claims that were medically necessary were entitled to reimbursement.

24. Medicaid and Medicaid MCOs provided prescription drug coverage for many of their members, paying for some or all of the cost of drugs that physicians prescribed for their members, but only if those prescriptions were medically necessary. Controlled substance prescriptions that were written outside the usual course of medical practice and not for a legitimate medical purpose were medically unnecessary and ineligible for payment.

COUNTS 1 – 12
(Health Care Fraud, 18 U.S.C. § 1347)

The First Assistant United States Attorney charges:

25. The factual allegations of paragraphs 1 through 24 of this Information are re-alleged and incorporated by reference as though fully set forth herein.

26. From in or around March 2016 through in or around February 2021, in the Northern District of Ohio, Eastern Division, Defendant STEVEN J. ARNOLD did devise and intend to devise a scheme and artifice to defraud federal health care benefit programs in connection with the delivery of and payment for health care benefits, items, and services.

Purposes of the Scheme

27. The purposes of the scheme included, but were not limited to, the following: for Defendant to unlawfully enrich himself by (1) attracting and maintaining patients seeking prescriptions for medically unnecessary controlled substances, and (2) obtaining reimbursement for office visits from health care benefit programs for visits in which Defendant issued prescriptions for medically unnecessary controlled substances.

Manner and Means of the Scheme

28. The manner and means by which Defendant carried out the scheme included, but were not limited to, the following:

a. Defendant prescribed controlled substances—including high levels of opioids (often in excess of 200 MED, and sometimes in excess of 500 MED) combined with benzodiazepines—that were medically unnecessary and knowingly issued the prescriptions outside the usual course of professional practice and not for a legitimate medical purpose.

b. Defendant regularly prescribed narcotics without first obtaining a proper diagnosis, considering the risks of abuse or misuse, or establishing goals of treatment.

c. Defendant continued prescribing and escalating doses without documented patient improvement and despite obvious signs of patient misuse, including inconsistent UDS results and patient harm, including patient overdose and decline.

d. Defendant often failed to order UDSs when he knew that he should do so.

e. Defendant's prescriptions for medically unnecessary controlled substances caused prescription drug claims to be billed to healthcare benefit programs, which would not have been covered but for Defendant's fraudulent representation that the substances prescribed were medically necessary.

f. Defendant required patients to attend regular office visits in order to obtain medically unnecessary prescriptions, and Defendant submitted and caused to be submitted to health care benefit programs claims for payment for those medically unnecessary office visits, which would not have been covered but for Defendant's fraudulent representation that the office visits were medically necessary.

Execution of the Scheme

29. On or about the dates listed below, in the Northern District of Ohio, Eastern Division, Defendant STEVEN J. ARNOLD knowingly and willfully executed and attempted to execute the above-described scheme and artifice to defraud health care benefit programs as defined in Title 18, United States Code, Section 24(b), that is, the following Medicaid MCOs, in connection with the delivery of and payment for health care benefits, items, and services, that is, reimbursements for the following medically unnecessary prescribed controlled substances, by issuing the following prescriptions and therefore causing the submission of the claims for reimbursement for those medically unnecessary prescribed controlled substances, each submission constituting a separate count of this Information:

Count	Beneficiary	Claim Date	MCO	Prescribed Substance
1	Patient 1	3/4/2016	MCO 1	Hydrocodone-Acetaminophen
2	Patient 1	3/4/2016	MCO 1	Oxycodone
3	Patient 1	3/4/2016	MCO 1	Diazepam

Count	Beneficiary	Claim Date	MCO	Prescribed Substance
4	Patient 2	11/14/2016	MCO 2	Oxycodone
5	Patient 2	11/14/2016	MCO 2	Alprazolam
6	Patient 3	11/16/2018	MCO 2	Oxycodone
7	Patient 3	11/16/2018	MCO 2	Alprazolam
8	Patient 3	11/16/2018	MCO 2	Pregabalin
9	Patient 4	3/22/2019	MCO 2	Oxycodone-Acetaminophen
10	Patient 4	3/22/2019	MCO 2	Oxycodone
11	Patient 5	6/24/2019	MCO 1	Methadone
12	Patient 5	6/24/2019	MCO 1	Alprazolam

All in violation of Title 18, United States Code, Section 1347.

MICHELLE M. BAEPPLER
First Assistant United States Attorney

By: Michael L. Collyer
MICHAEL L. COLLYER
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